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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,310	03/01/2000	Yao-Zhong Lin	22000.0021U2	3622

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NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/516,310	LIN ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,9-26,33 and 40* is/are pending in the application.

4a) Of the above claim(s) *16-26 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,9-15 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2006 has been entered.

This Office Action is a reply to the Paper filed 16 October 2006 in response to the Final Office Action mailed 13 June 2005 and the Advisory Action mailed 18 January 2006. Claims 16-26 and 33 had been withdrawn from consideration and claims 6 and 9-15 were considered in the 13 June Office Action. Claim 40 was added in the 16 October Paper. Claims 6, 9-26, 33 and 40 are pending and claims 6, 9-15 and 40 are under consideration.

Response to Arguments

Rejections under 35 U.S.C. §112, first paragraph, (enablement):

Claims 6, 10, 11, 13-15 and 40 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of importing a peptide, polypeptide or protein into a cell of a subject comprising administering to the subject a complex comprising the peptide, polypeptide or protein linked to a mammalian hydrophobic importation competent signal peptide comprising SEQ ID NO: 5, does not reasonably provide enablement for the method practiced with any mammalian hydrophobic importation competent signal peptide as broadly claimed. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This rejection is maintained for the reasons stated in previous Office Actions and for the reasons set forth herein below in the response to Applicant's arguments.

It is first noted that Applicant argues persuasively that the previous rejection based on a lack of enablement for therapeutic application of the claimed method is **withdrawn**. Applicant argues persuasively that the claims do not require a therapeutic outcome. One of ordinary skill would recognize that the method could be used in a research setting to determine the effect of delivering a given peptide, polypeptide or protein into a cell of a subject. Thus, although the Office maintains that the disclosure is not enabling for the therapeutic use contemplated in the specification, the method as a whole is enabled for other *in vivo* applications that would be readily apparent to one of skill in the art.

In addition, the rejection based on a lack of enablement for delivering any peptide, polypeptide or protein into a cell is **withdrawn**. Applicant cites the teachings of Jo et al. (2005) *Nature Med.* 11: 892-898, who demonstrates that the K-FGF signal peptide (i.e., the instant SEQ ID NO: 5) is capable of delivering a 225 amino acid SOCS3 protein into a cell (see especially Figure 1 and the caption thereto) and cites the teachings of Jo et al. (2001) *Nature Biotechnol.* 19:929-933, who demonstrates that the K-FGF signal peptide is capable of delivering a full-length Cre recombinase into a cell (see especially Figures 1 and 2 and the captions thereto). Furthermore, Applicant cites US Patent No. 6,841,535, which teaches that properly configured importation competent peptides can deliver proteins such as GFP and p27(kip1) into cells. The peptides described in the '535 patent are the active ingredient in the Chariot™ kit, which is also

demonstrated to be capable of delivering a variety of large proteins such as the 119 kDa subunit of β-galactosidase and antibody molecules into cells. (See the Product Information for Chariot™, htpp://www.activemotif.com/catalog/cell_biology/chariot.) In view of this, the skilled artisan would reasonably expect that the importation competent peptide comprising the instant SEQ ID NO: 5 could be used to import a variety of peptides, polypeptides and proteins into a cell in a subject.

However, for the reasons set forth in the previous Office Actions and herein below in response to Applicant's arguments, one of ordinary skill in the art would not be able to practice the claimed method using any "importation competent signal peptide" as broadly defined in the instant application.

In response to the arguments of record, Applicant first contends that only a single use of the invention is required for enablement and all that is required in the instant case is that one of skill choose a signal peptide as described in the specification and a peptide, polypeptide or protein to be imported. Applicant asserts that any selected signal peptide can be tested for its ability to function as an importation competent signal peptide using routine screening methods. Applicant contends that identification of additional importation competent signal peptides is routine experimentation and is not undue. Applicant further cites an exhibit KK which is purported to list over 500 signal peptides that have been experimentally verified to act as signal peptides. Applicant contends that each of the signal peptides is hydrophobic and importation competent.

These arguments have been fully considered but are not deemed persuasive. As repeatedly pointed out in prosecution, the specification defines an "importation competent signal peptide" as "a sequence of amino acids generally of a length of about 10 to 50 or more amino acid residues, many (typically about 55-60%) residues of which are hydrophobic such that they have a hydrophobic, lipid-soluble portion...The signal peptides of this invention, as discovered herein, are also importation competent." Thus, the application seeks to claim a method of using any peptide having more than about 10 amino acids and typically, but not limited to, 55-60% are hydrophobic residues to import proteins into cells *in vivo*. As pointed out in the Office Action mailed 17 September 2004, "the standard for enablement is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.* (224 USPQ 409, 414)". Applicant's position completely ignores the scope of protection sought and the fact that the disclosure and the relevant art as of the effective filing date of the instant application provided only a single example of an "importation competent signal peptide" as defined in the specification.

In the remarks, Applicant's representative asserts that all signal peptides in the SIGPEP database are importation competent, but fails to provide any evidence to support this contention. It is noted however, that a review of the SIGPEP database did not turn up any statement that the peptides disclosed in the database are importation competent. It is also noted that the specification does not contain any teaching that all peptides in the SIGPEP database are importation competent. Instead, the specification teaches, in a discussion of signal peptides, "In eukaryotes, newly synthesized proteins in the cytoplasm are targeted to the ER membrane by

signal sequences that are recognized generally by the signal recognition particle (SRP) and its ER membrane receptors. This targeting step is followed by the actually transfer of protein across the ER membrane and out of the cell through the putative protein-conducting channel. In bacteria, the transport of most proteins across the cytoplasmic membrane also requires a similar protein-conducting channel.[] On the other hand, signal peptides can interact strongly with lipids, supporting the proposal that the transport of some secretory proteins across cellular membranes may occur directly through the lipid bilayer in the absence of any proteinacious channels." (Pages 2-3, citations omitted.) Thus, the specification teaches that what was known in the art was that translocation of most proteins across cellular membranes via a signal peptide dependent mechanism required a protein-conducting channel and speculates that some secretory proteins might cross cellular membranes directly through the lipid bilayer. The specification does not teach that all signal peptides are importation competent, which is defined on page 11 of the specification as "capable of penetrating through the cell membrane from outside the cell to the interior of the cell".

Furthermore, the only discussion of the SIGPEP database in the specification is found at page 11, wherein the disclosure speculates that information obtained from the database can be used to target certain cell types by using signal peptides from proteins expressed in the targeted cell. This teaching is quite different from the present statement by Applicant's representative that all signal peptides in the SIGPEP database are importation competent and Applicant's assertions in prosecution that the importation competent signal peptides of the instant claims enter cells by a passive diffusion mechanism[1].

[1] See the discussion of Lindgren et al. and Veach et al. in on page 11 of the remarks filed 19 December 2005.

Thus, the disclosure does not assert that all signal peptides in the SIGPEP database are importation competent. Instead, the specification teaches that most signal peptides require the SRP and protein conductance channels, which are structures found in the ER membrane. (See the discussion of Redman et al. at pages 7-8 of the Office Action mailed 13 June 2005.) This is not consistent with the unsubstantiated assertion by Applicant's representative that all peptides in the SIGPEP database are "importation competent" (i.e., capable of penetrating through the cell membrane from outside the cell to the interior of the cell).

Finally, with regard to the structural features set forth in the disclosure, which amount to no more than a stretch of ten or more amino acids comprising approximately 50% hydrophobic residues, US Patent 6,841,535 (cited as exhibit B in Applicant's remarks and relied upon to evidence enablement for the instant claims), teaches, based on a careful empirical analysis of importation competent peptides, "With regard to the hydrophobic domain, its is clear from the results of transfection experiments using Peps-1.4 and -2.10, the hydrophobic domain alone is not sufficient to transfect drugs, proteins or peptides." (Column 53, ll. 5-9, emphasis added.) Thus, the post filing art evidences that the vague structural specifications disclosed in the instant application do not define a peptide as importation competent.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Specifically, in view of the tremendous scope of the importation competent signal peptide of the claims and the very limited knowledge of the structural properties required for importation competence available at the time of filing, identifying those embodiments within the scope of the claims that were conceived but not yet made would clearly require undue experimentation. Therefore, the disclosure fails to enable the invention beyond the

scope of the method practiced using an importation competent signal peptide comprising SEQ ID NO: 5.

Rejections under 35 U.S.C. §112, first paragraph, (possession):

Claims 6, 10, 11 and 13-15 **stand rejected** and newly added claim 40 **is rejected** under 35 USC 112, first paragraph for insufficient written description for reasons of record and herein below.

The previous Office Action asserts that a recitation of functional characteristics alone does not provide adequate written description for a molecule but must be coupled with a known or disclosed correlation between function and structure.

In response to the *prima facie* case and arguments of record, Applicant first contends that the structural feature "hydrophobic region" is a structural limitation that adequately describes the importation competent peptide of the claims. Applicant cites the teachings in the specification that vaguely asserts that the importation competent signal peptide comprises more than approximately 10 amino acids and typically, but not exclusively, 55-60% hydrophobic residues. Applicant also cites the teaching in the specification that the hydrophobic portion is a common major motif of the signal peptide. Furthermore, Applicant points to teachings in the specification regarding the SIGPEP database and asserts that there are over 500 sequences in the SIGPEP database that fit the description of an importation competent signal peptide.

These arguments have been fully considered but are not deemed persuasive. As pointed out above, US Patent 6,841,535 teaches, based on a careful empirical analysis of importation competent peptides, "With regard to the hydrophobic domain, its is clear from the results of

transfection experiments using Peps-1.4 and -2.10, the hydrophobic domain alone is not sufficient to transfect drugs, proteins or peptides." (Column 53, ll. 5-9.) Thus, the presence of a "hydrophobic region" alone is not sufficient to make an peptide importation competent and the vague teachings of the specification cannot be considered a description of the relevant identifying characteristics of an importation competent signal peptide. Furthermore, as discussed in previous Office Actions, Applicant's assertion that all that is required for importation competence is a "hydrophobic region" is inconsistent with Applicant's own teachings in the post filing art. For example, in answering the question, "How does SSHR, with its positively charged cargo, pass through the membrane phospholipid bilayer?", Veach et al. (2004) *J. Biol. Chem.* 279:11425-11431 (previously made of record) postulates two mechanisms, i.e. a looping-unlooping mechanism and a tilted peptide mechanism. (See especially Figure 5 and the caption thereto and the first full paragraph on page 11430.) Both of these mechanisms are based on a helical structure of signal peptide and the presence of a proline within the sequence as a helix-bending residue to form a "helical hairpin". Neither of the structures that form the basis for the mechanisms proposed by Veach et al. are contemplated in the instant application. The post-filing teachings of the '535 Patent and Veach et al. clearly evidence that the structure that defines the function of an importation competent signal peptide is more complex than the mere presence of about 55% hydrophobic residues in a 10 amino acid sequence and that the critical structures are not disclosed in the instant application.

With regard to the applications disclosure of the SIGPEP database, as discussed above Applicant's representative provides no basis for the assertion that all signal peptides disclosed in the SIGPEP database are importation competent and a review of the SIGPEP database did not

turn up any statement that the peptides disclosed in the database are importation competent. It is also noted that the specification does not contain any teaching that all peptides in the SIGPEP database are importation competent. Instead, the specification teaches, in a discussion of signal peptides, "In eukaryotes, newly synthesized proteins in the cytoplasm are targeted to the ER membrane by signal sequences that are recognized generally by the signal recognition particle (SRP) and its ER membrane receptors. This targeting step is followed by the actually transfer of protein across the ER membrane and out of the cell through the putative protein-conducting channel. In bacteria, the transport of most proteins across the cytoplasmic membrane also requires a similar protein-conducting channel.[] On the other hand, signal peptides can interact strongly with lipids, supporting the proposal that the transport of some secretory proteins across cellular membranes may occur directly through the lipid bilayer in the absence of any proteinacious channels." (Pages 2-3, citations omitted.) Thus, the specification teaches that what was known in the art was that translocation of most proteins across cellular membranes via a signal peptide dependent mechanism required a protein-conducting channel and speculates that some secretory proteins might cross cellular membranes directly through the lipid bilayer. The specification does not teach that all signal peptides are importation competent, which is defined on page 11 of the specification as "capable of penetrating through the cell membrane from outside the cell to the interior of the cell".

Furthermore, the only discussion of the SIGPEP database in the specification is found at page 11, wherein the disclosure speculates that information obtained from the database can be used to target certain cell types by using signal peptides from proteins expressed in the targeted cell. This teaching is quite different from the present statement by Applicant's representative that

all signal peptides in the SIGPEP database are importation competent and Applicant's assertions in prosecution that the importation competent signal peptides of the instant claims enter cells by a passive diffusion mechanism.

Thus, the disclosure does not assert that all signal peptides in the SIGPEP database are importation competent. Instead, the specification teaches that most signal peptides require the SRP and protein conductance channels, which are structures found in the ER membrane. (See the discussion of Redman et al. at pages 7-8 of the Office Action mailed 13 June 2005.) This is not consistent with the unsubstantiated assertion by Applicant's representative that all peptides in the SIGPEP database are "importation competent" (i.e., capable of penetrating through the cell membrane from outside the cell to the interior of the cell).

Next, Applicant again asserts that the signal peptides of the instant claims are not new and asserts that the importation competent signal peptides, like the cells of *Amgen Inc. v. Hoechst Marion Roussel, Inc.* are well known biological materials, well classified and easily recognized by those of skill in the art. This Argument has been fully considered but is not deemed persuasive because it again rests on the unsubstantiated assertion of Applicant's representative that what is known in the art as a "signal peptide" is equivalent to the "importation competent signal peptide" of the instant claims. As described above, there is no such assertion made in the instant specification and, in fact, the teachings of the specification appear to endorse a mechanism of translocation for most signal peptide bearing proteins that involves protein structures of the ER membrane, which would not be present in eukaryotic cell plasma membranes such that the mechanism of translocation across the ER membrane can be extended to translocation from outside of the cell to the interior of the cell. In addition, it is noted that the

importation competent signal peptide of the instant claims is not limited to comprising all of the structural elements of a "signal peptide" as that term is commonly understood regarding export of proteins via the ER. Instead, the specification defines an importation competent signal peptide as any peptide of about 10 or more amino acids and a hydrophobic region which might comprise 55-60% hydrophobic residues, which peptide is importation competent. As clearly evidenced by the post filing art, this disclosure is not a description of an importation competent signal peptide, rather it is a wish to know the identity of any peptide having the function of an "importation competent signal peptide".

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C.§112, first paragraph, as lacking adequate written description.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, Applicant seeks to claim a method of using a signal peptide selected from the SIGPEP database. Although the specification contemplates selecting signal peptides from the SIGPEP database, the scope of peptides in the SIGPEP database is larger now than it was at the time the application was filed. For example, the SIGPEP database now includes the signal peptide of Swiss-Prot entry Q6UW56, which was integrated into Swiss-Prot[2] on 21 June 2005, well after the instant application was filed. As the limitation "selected from the SIGPEP database" embraces subject matter beyond the scope of the subject matter of the application as filed, limitation encompasses impermissible new matter.

[2] SIGPEP entries are derived from the Swiss-Prot database.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 contains the trademark/trade name SIGPEP database. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a set of signal peptides from which the importation competent signal peptide of the claims is selected and, accordingly, the identification/description is indefinite.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636